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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

HANMI'S OPPOSITION TO ASTRAZENECA'S MOTION TO PRECLUDE DEFENDANT'S EXPERT DR. ATWOOD FROM RELYING ON EVIDENCE FIRST IDENTIFIED IN HIS REPLY EXPERT REPORT (*i.e.*, TEST REPORTS AND OPINIONS OF DRS. KIRSCHNING AND HÖRNCHEN AND PROF. BRAUN)

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AstraZeneca seeks to preclude Hanmi from presenting selected rebuttal evidence relating to the enablement of a prior art patent, Kohl DE '455. (D.I. 296). Put simply, AstraZeneca urges that Kohl is not enabled and therefore is not pertinent prior art, but at the same time seeks to preclude Hanmi from telling the Court that persons of skill in the art were able to make and use the claimed compound by following the teachings of Kohl. The evidence relied on by Dr. Atwood is timely rebuttal testimony and poses no undue prejudice to AstraZeneca. AstraZeneca's motion should be denied.

I. Dr. Atwood's Opinions Regarding the Test Reports and Opinions of Drs. Kirschning and Hörnchen and Professor Braun are Timely

AstraZeneca seeks to preclude evidence regarding the enabling disclosure of Kohl because Dr. Atwood's presentation was purportedly untimely or "belatedly identified." D.I. 296 at 7. However, AstraZeneca's arguments concerning non-enablement of Kohl (an issue where AstraZeneca bears the burden) in Dr. Davies' Rebuttal Report of March 25, 2013 necessitated Dr. Atwood to present such opinions and evidence.

In its initial invalidity contentions served May 25, 2011, Hanmi detailed the Kohl DE '455 disclosure of each and every limitation of the asserted claims of the '504 and '192 Patents and, alternatively, the bases as to how Kohl renders obvious the asserted claims. *See* D.I. 87-1, Hanmi's Initial Invalidity contentions, dated May 25, 2011, pp. 84-93.[1] In line with Hanmi's contentions, Dr. Atwood in his Opening Expert Report opined that Kohl DE '455 anticipates the '504 Patent claims (¶¶81-133) and the '192 Patent claims (¶¶134-142) or alternatively renders

[1] Hanmi was permitted to amend its contentions on December 9, 2011 (D.I. 145) in response to AstraZeneca's assertion of claims 3, 5 and 10 against Hanmi and also properly moved the Court (L.Pat. R. 3.6, 3.7, D.I. 238) for, and was granted leave to, amend its contentions a second time for the purpose of conforming its contentions to the summary judgment record (D.I. 269).

the claims obvious (¶¶143-154). *See* D.I. 290-9, Opening Report of Dr. Jerry Atwood, dated February 19, 2013.

AstraZeneca responded in its Responses to Hanmi's Invalidity Contentions that Kohl DE '455 is non-enabling on the following bases:

- DE '455 does not enable the preparation of (-)-omeprazole in at least 94% ee because Example 5 generates the precursor to (+)-omperazole in about 90-92% diastereomeric excess. AstraZeneca referencing the EP Opposition proceedings, stated that the DE '455 inventors had "attempted to enhance the optical purity of this partially resolved (+)-omeprazole by recrystallization, but all attempts failed." *Id*. at pp. 11. In another paragraph, AstraZeneca generally stated that scientists at AstraZeneca made three attempts to produce the (+)-enantiomer, and failed. *Id*.

- DE '455 does not enable the preparation of "pure" (-)-omperazole because the process of Kohl Example 6 contains residual solvents, and other products of chemical degradation. AstraZeneca also mentioned that "the DE '455 inventors were unable to recrystallize the (+)-omeprazole from Example 6, preventing purification." *Id*. at pg. 12.

See D.I. 297, AstraZeneca's Amended Responses to Hanmi's Invalidity Contentions, dated March 19, 2012, pp. 9-12.

AstraZeneca went well beyond its contentions and posited in its Rebuttal Report of Dr. Davies on March 25, 2013, stating that Kohl DE '455 was not enabled based on, in particular, testimony borrowed from the EP opposition of the Kohl inventors and, in addition, based on experiments conducted by Dr. Larsson, all of whom ostensibly were unable to reproduce the claimed compound. *See* Ex. 1, Rebuttal Report of Stephen G. Davies, Phil dated March 25, 2013, pp. 41-61 and pp. 69-89. Dr. Davies spends nearly *forty pages* in his rebuttal report opining that Kohl is not enabled, relying on experiments of others, where little to no such mention was made in AstraZeneca's Amended Contentions apart from a few generic arguments and citations in footnotes. *Compare* AstraZeneca's Amended Responses to Hanmi's Invalidity

Contentions, dated March 19, 2012, pp. 9-12 (D.I. 297) *with* Dr. Davies Rebuttal Report, pp. 41-61 and pp. 69-89 (Ex. 1).

Faced with these elaborate facts and opinions, Dr. Atwood properly responded to Davies' reliance on the Kohl and Larsson experiments in his Reply Report. *See* Ex. 2, Reply Report of Atwood, ¶¶ 29-54. Dr. Atwood responded to Dr. Davies's testimony about Kohl and opined that, contrary to Dr. Davies' opinion, Dr. Kohl was able to successfully produce an enantiomer of omeprazole and any "failed" attempts by Drs. Kohl and Larsson are attributable to their deviations from the teaching of the Kohl DE '455 patent disclosure. *Id.*

Moreover, Dr. Atwood's testimony regarding the experiments and reports by Drs. Kirschning, Hörnchen and Professor Braun was presented to establish that Dr. Davies failed to consider experiments by others who were successfully, without undue experimentation, able to reproduce the enantiomers of omeprazole in high optical purity. *Id.* at ¶¶14-28. Such evidence is proper rebuttal testimony that explains or disproves evidence set forth by AstraZeneca. *See United States v. Stitt*, 250 F.3d 878, 897 (4th Cir. 2001) (defining rebuttal evidence as "[e]vidence given to explain, repel, counteract, or disprove evidence offered by the adverse party."); *see also* Fed. R. Civ. P. 26(a)(2)(D) (rebuttal experts provide testimony to "solely contradict or rebut evidence on the same subject matter identified by [an opposing party's expert witness]."). In light of the *de minimis* attention given to these issues as mere asides in AstraZeneca's contentions (in contrast to the dramatic exposition of argument and evidence in Dr. Davie's Rebuttal Report), Dr. Atwood properly responded to these matters in his April 8, 2012 Reply Report.

Further, Dr. Atwood was not required to present any testimony on the enablement of the Kohl patent in his Opening Report since it is well established that it is **not the burden of**

accused infringer to prove that a prior art patent is enabling. *See Amgen, Inc. v. Hoechst*, 314 F.3d 1313, 1355 (Fed. Cir. 2003) ("a court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled…. Therefore, it was Amgen [the patentee] who bore the burden of proving the non-enablement of Sugimoto [the prior art patent] before the district court. TKT [the accused infringer] did not bear a burden of proving enablement."). Because AstraZeneca had the burden of proof to establish non-enablement of Kohl, Dr. Atwood was not required to address or present any evidence regarding the enabling disclosure in his initial report. AstraZeneca's motion *in limine* improperly seeks to shift the burden of proof on Hanmi by suggesting that Hanmi should have presented evidence of enablement in its Opening Reports. This is contrary to the Federal Rules and case law and thus should be rejected.

II. The Testimony Offered by Dr. Atwood is Fair, is Helpful to the Court, and is Not Unduly Prejudicial to AstraZeneca

AstraZeneca also argues that it will be "severely prejudiced" if Hanmi is permitted to rely on evidence that others skilled in the art were able to successfully replicate the claimed compounds following the disclosure of Kohl. AstraZeneca cannot have it both ways – argue the non-enablement of prior art patent, then try to keep out Hanmi's rebuttal evidence on this same issue.

Dr. Atwood's reliance on the Declarations and test reports of Drs. Hörnchen, Kirschning and Professor Braun is proper and necessary given Dr. Davies' reliance on the work of others. Experts routinely rely on the work of others, and such reliance is not improper. *See* Fed. R. Evid. 703. An expert appropriately may rely upon reports of others to formulate his opinion, and

such reliance is often an indicia of reliability. *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 588 (7th Cir. 2000) ("Indeed, courts frequently have pointed to an expert's reliance on the reports of others as an indication that their testimony is reliable"). An expert witness may rely upon hearsay information if that information is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Fed. R. Evid. 703. *See U.S. v. Mulder,* 273 F.3d 91, 102 (2d Cir. 2001) ("expert witnesses can testify to opinions based on hearsay or other inadmissible evidence if experts in the field reasonably rely on such evidence in forming their opinions"); *Rondout Valley Cent. Sch. Dist. v. Coneco Corp.,* 321 F. Supp.2d 469, 479 (N.D.N.Y. 2004) (facts on which expert relies upon need not be admissible in evidence for his opinion to be admitted; expert economist may rely upon "data that he did not personally collect").

AstraZeneca's only argument for excluding this relevant evidence – that it will not have the opportunity to cross-examine the witnesses – is unavailing. The declarations and test reports of Drs. Hörnchen, Kirschning and Professor Braun were previously submitted in the European Opposition to AstraZeneca's corresponding EP patents. Dr. Davies had previously seen and commented on the Declarations and test reports in the EP Opposition. *See* Ex. 3, Declaration of Stephen G. Davies, dated April 4, 2011 (HAN0041092-41100). Thus, AstraZeneca cannot fairly say that such testimony is new or surprising. Additionally, Dr. Davies filed a sur-reply in this litigation fully setting forth his opinions regarding the declarations and test reports of Drs. Hörnchen, Kirschning and Professor Braun. *See* D.I. 296-2, The Sur-Reply Expert Report of Stephen G. Davies, D. Phil. Concerning Validity, dated April 17, 2013. Certainly, any suggestion of prejudice to which AstraZeneca might arguably have had has been cured by

Dr. Davies' sur-reply and his past experiences in the European Opposition, where he fully briefed and addressed the same issues presented in this case.

Indeed, if any party faces unfair prejudice, it is Hanmi, were this motion to be granted. AstraZeneca seeks to block this relevant rebuttal evidence not because it is inadmissable, but because it refutes AstraZeneca's claim that the method described in Kohl is not enabled. As such, the subject testimony of Dr. Atwood is both fair and helpful to the trier of fact. Fed. R. Evid. 702.

III. Dr. Atwood's Testimony is Permissible

AstraZeneca also argues that the testimony of Prof. Braun and Dr. Kirschning should be excluded at trial because their opinions are inadmissible hearsay. However, Dr. Atwood does not rely on the testimony of Dr. Kirschning and Professor Braun for the truth of the matter asserted, but rather to opine that he reviewed their experiments and believes, in his expert opinion, that the doctors prepared the compounds following the teaching of Kohl.[2] This is permissible expert testimony from a qualified chemist, like Dr. Atwood.

Even if the underlying evidence was "inadmissible," it is well-established that an expert may rely on secondhand information (facts or data made known to the expert before trial through means other than his or her own perception – *e.g.*, reports, studies, literature, patient statements, etc.) even if such information is inadmissible. Fed. R. Evid. 703, Adv. Comm. Notes; *see*

[2] AstraZeneca cites to *Tokio Marine v. Norfolk & Western Ry. Co*., 1999 US App. LEXIS 476 (4th Cir. January 14, 1999), for the proposition that Dr. Atwood's testimony is impermissible hearsay. In *Tokio Marine*, the court excluded evidence of an appraisal report of a nontestifying witness, which was offered as evidence of the appraisal value of cars. In this case, Dr. Atwood does not "adopt" the testimony of Hörnchen, Kirsching and Braun as AstraZeneca complains based on *Tokio Marine*. Rather, Dr. Atwood's testimony simply is that he reviewed the experiments of Hörnchen and Kirschning and believes, in his expert opinion, that the doctors prepared the compounds following the teaching of Kohl.

Jaasma v. Shell Oil Co., 412 F.3d 501, 513-14 (3rd Cir. 2005) (opinion may be based on data reasonably relied on by other experts in the field without independent testing). An expert witness may rely on hearsay and/or unauthenticated evidence. *Boone v. Moore,* 980 F.2d 539, 542 (8th Cir. 1992). In addition, questions relating to the bases and sources of an expert's opinion generally affect the weight to be given the testimony, not its admissibility, and are left for the factfinder's consideration. *First Union Nat'l Bank v. Benham*, 423 F.3d 855, 862 (8th Cir. 2005).

Moreover, such evidentiary issues and the *Daubert* screening requirement are less important in bench trials, in which "the usual concerns of the (*Daubert*) rule – keeping unreliable expert testimony from the jury – are not present." *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010). Here, there is no risk of confusion in permitting the testimony of Dr. Atwood in this bench trial.

IV. AstraZeneca Should Be Precluded From Relying On Testimony and Evidence For Which It Has Not Produced Samples And Documentation of Experimental Work

Throughout this action, AstraZeneca has consistently relied on the testimony, declarations, and experimental work of third parties in support of its efforts to show that the DE '455 reference is non-enabling. Even Dr. Davies and its other experts rely on declarations and experimental testing by, *e.g.*, Kohl, Larsson, Senn-Bilfinger, etc. that was carried out years ago in conjunction with the European opposition proceedings. *See* Ex. 1, Rebuttal Report of Stephen G. Davies, D. Phil, on Validity, dated March 25, 2013 at ¶¶101-140. Ironically, AstraZeneca seeks to preclude the same types of materials from Dr. Atwood's Reply Report that it and its experts expressly rely on in the present case.

There is no serious dispute that the European Opposition proceedings and the testimony of declarants concerning their work has long been a part of this case. (*See* D.I. 113-2, AstraZeneca July 25, 2011 Responses to Hanmi's Invalidity and D.I. 133, 176, 207, AstraZeneca *Markman* briefing incorporating by reference as if fully set forth therein numerous declarations discussing declarant and third party experimental work (see below); *see also* D.I. 87-1, Hanmi's May 25, 2011 Non-infringement and Invalidity Contentions and Ex. 10, Hanmi's Preliminary Claim Construction and Supporting Evidence charts citing EP Oppositions at p. 5 (the entirety of the EP Proceedings as of August 25, 2011 was produced to AstraZeneca on the that date (*see* Ex. 11)).) Consistent with that fact, AstraZeneca's papers and expert reports are riddled with reliance on the prior testimony and work of its own witnesses and third parties, documentation and samples of which have not been produced to Hanmi in the course of this action. By way of example:

1. AstraZeneca's July 25, 2011 Responses to Hanmi's Invalidity Contentions, incorporating all of the following by reference as though set forth therein (*see* D.I. 113-2, p. 1, n.1; *see also* p. 5, n. 19, 20):

    - Andersson Canadian Affidavit, February 17, 2009 (AZ0002251649-775)
    - Larsson EPO Declaration, November 4, 2008 (AZ0002237724-34)
    - Kohl EP Declaration, September 5, 2008 (AZ0002357049-126) ;
    - Kohl Canadian Affidavit, February 13, 2009 (AZ0002252004-78));
    - Senn-Bilfinger EP Declaration, September 23, 2008 (AZ0002237753-58))
    - Lindberg Israel Declaration, August 17, 2004 (AZ0001323665-711));
    - Davies Canadian Affidavit, February 17, 2009 (AZ0002252395-475) Davies EU Declaration April 8, 2009 (AZ0002270355-66) *(id.)*;
    - Davies Denmark Declaration November 17, 2009 (AZ0002279031-95);
    - Davies EPO Declaration December 3, 2010 (AZ0005144446-483);
    - Levy EP Opinion (May 19, 2006) and Response submission (December 6, 2006), (AZ0002291364-403; AZ0001543419-423);
    - Levy Canadian Affidavit, February 17, 2009 (AZ0002251835-943)

2. AstraZeneca's *Markman* submissions of November 7, 2011 (D.I. 133), January 6, 2012 (D.I. 176), March 19, 2012 (D.I. 207)

- Andersson Declaration, February 12, 1997 (AZ0005000153-166)
- Larsson Declaration, November 7, 2008 (AZ0002237724-734) D.I. 208-10 - D.I. 208-14
- Senn-Bilfinger Declaration , September 23, 2008(AZ0002237753-758) D.I. 208-1)
- Kohl Declaration, September 5, 2008 (AZ0002357049-065) D.I. 208-2- D.I. 208-7)

3. AstraZeneca's Expert Reports

- Von Unge EPO Declaration, November 5, 2008 (AZ0002251165- AZ000225121 (Davies Rebuttal Report, p. 28; Bartlett Rebuttal Report, pp. 49-50)
- Von Unge EPO Declaration, August 29, 2012 (Davies Rebuttal Report, p. 60)
- Senn Bilfinger EPO Declaration, September 23, 2008 (Davies Rebuttal Report, pp. 31)
- Davies EU Declaration, April 8, 2009 (AZ0002270356- AZ0002270366) (Davies Rebuttal, p. 31)
- Davies Denmark Declaration, November 16, 2009 (AZ0002279031-AZ0002279095) (Davies Rebuttal Report, p. 31)
- Davies EPO Declaration, December 3, 2009 (Davies Rebuttal Rep. p. 31).
- Davies EPO Declaration, April 4, 2011(Davies Rebuttal Report, p. 31).
- Kohl Canadian Declaration, September 5, 2008 (AZ0002252004-AZ0002252078), Davies Rebuttal Report, p. 31)
- Kohl Declaration, September 5, 2008 (AZ0002525288-AZ0002525307) (Bartlett Report, pp. 48-49)
- Larsson EPO Declaration November 4, 2008 (Davies Rebuttal Report, p.50). (AZ0002237724-AZ0002237734)
- Astra Analytical Report, H 199/18 Magnesium, January 19, 1999 (Byrn Opening Report, p. 40)
- Astra Physicochemical data, H 199/18 magnesium trihydrate, October 14, 1998 (Byrn Opening Report, p. 40)
- Select excerpts von Unge lab notebook, H199/18 (with English translation) AZ0000386558 - AZ0000386559 (Byrn Rebuttal Report, pp. 20, 26)
- Select excerpts von Unge lab notebook, H199/18 AZ0000389819 (Byrn Rebuttal Report, pp. 20, 26)

Under these circumstances, AstraZeneca's motion to preclude testimony of Dr. Atwood, while at the same time intending to proceed with its own reliance on the prior work and testimony of select others, ***for which original samples and underlying experimental work documentation have not been produced*** to Hanmi is disingenuous and epitomizes trial by ambush. *APP Pharms. LLC v. Ameridose, LLC,* 2011 WL 6325975, *1 (D.N.J. Dec. 6, 2011).

Such tactics have severely prejudiced Hanmi. If AstraZeneca had not, through its reliance on the work of others throughout this case, effectively concealed its plan to block presentation of EP declarant testimony and work performed by these individuals, Hanmi could have sought to independently have this work replicated and pressed AstraZeneca to do the same for all of the above identified evidence it seeks to rely pursuant to its improper discordant standards. Neither AstraZeneca or any of its witnesses have produced samples that form the basis of all of the experimental work reported upon in the declarations relied upon by AstraZeneca's witnesses. Nor has AstraZeneca produced any data underlying its declarants' experiments beyond what was contained in the public record of the European opposition proceedings. If AstraZeneca's motion *in limine* is granted, fairness demands that same standard apply to AstraZeneca and that it be precluded from relying on, or presenting at trial, the foregoing testimony and evidence.

If the Court is inclined is to grant AstraZeneca's motion to exclude, Hanmi requests that the aforementioned materials and testimony be excluded.

V. Conclusion

For the foregoing reasons, Hanmi respectfully requests that AstraZeneca's motion be denied.

Dated: May 6, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2013, I caused a copy of the foregoing **Hanmi's Opposition to AstraZeneca's Motion to Preclude Defendants' Expert Dr. Atwood From Relying on Evidence First Identified In His Reply Expert Report (i.e., Test Reports And Opinions Of Drs. Kirschning And Hörnchen And Prof. Braun)** to be served upon the following counsel by electronic mail:

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